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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/022,241	12/20/2001	Philippe Menei	017751-017	7151

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EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1618

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/022,241

Applicant(s)

MENEI ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-41 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 28-41 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) 3/25/2002
Paper No(s)/Mail Date 4/1/2005, 1/24/2002, 2/13/2002;
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

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DETAILED ACTION

Examiner acknowledges receipt of request for extension of time; request for continued examination filed under 37 CFR 1.114, amendment and remarks, all filed 04/01/05. Claims 28-41 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 04/01/05 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

4. Claims 28-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for mannitol, carboxymethylcellulose and polysorbate, does not reasonably provide enablement for all agents that qualify as isotonicity agent, all agents that are viscosity modifiers and all surfactants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention

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commensurate in scope with these claims. The protection sought in the recitation of surfactant, viscosity modifier and isotonicity agent is broader than that which is disclosed since polysorbate, carboxymethylcellulose and mannitol are the agents that the disclosure enables. There is no listing of viscosity modifying agents that are applicable in the instant invention except for carboxymethyl cellulose. There is no listing of surfactant agents that are applicable in the instant invention except for polysorbate. And there is no listing of isotonicity agents that are applicable in the instant invention except for mannitol. The generic claim to surfactant, viscosity modifier and isotonicity agent without indicating that agents apart from polysorbate, and carboxymethylcellulose and mannitol can work with the claimed invention places undue burden on the practitioner to come up with other surfactant, viscosity modifier and isotonicity agent that would work in the claimed invention.

Applicants may claim the specific surfactant, viscosity modifier and isotonicity agent that are enabled.

Claims 28-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitation "5-FU" in line 8 of claim 28 does not have antecedence since neither the sterile solution or the biodegradable microsphere contains the 5-FU. The 5-Fu ought to be present in the microsphere for the microsphere to release the 5-FU. Clarification is respectfully requested.

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However, claim 28 is examined as administering a suspension of biodegradable microspheres comprising 5-FU in a sterile solution that contains viscosity modifier, surfactant and isotonicity agent.

Double Patenting

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 28-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 7, 12-18, 21-23 and 26 of U.S. Patent No. 6,803,052. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 30, 33, 39, 40 and 41 are encompassed by issued claim 1 of US 6,803,052. The difference is that the issued patent recites amount of the 5-FU in percents while the examined application recites mg amounts. The person of ordinary skill in the art is able to relate amounts in mg and percents.

6. Claims 28-41 remain provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-15 of copending Application No. 10/451,216. The rejection will continue to be made until either the copending claims are amended so that the two sets of claim do not claim the same invention and at which time an evaluation will be made regarding obviousness type double patenting or the amended copending examined earlier filed application goes to issue.

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure (previously cited references).

Emerich et al. "Injectable Chemotherapeutic Microspheres and Glioma 11: Enhance Survival Following Implantation Into Deep Inoperable Tumors" *Pharmaceutical Research*, Vol. 17, no. 7, 2000, pages 776-781) discloses chemotherapeutic implantable, biodegradable polymer comprising carboplatin or BCNU for treating glioma and the carboplatin-loaded microspheres are injected into the center of the tumor (abstract). The microspheres are stereotactically injected into the tumors and the implantable biodegradable carboplatin loaded microsphere composition contains 0.9% saline, 0.1% TWEEN and 3% carboxymethylcellulose and the composition has a low viscosity (page 777). The biodegradable polymer inherently delays the release of the carboplatin. Administration of the carboplatin-loaded microsphere into the tumor would inherently maintain an effective concentration for a period of time including up to at least three weeks. In the absence of a showing of criticality, amounts of viscosity modifier and isotonicity agent and mg amount of biodegradable microspheres would not patentably distinguish the instant claims over the prior art that teaches the respective composition for treating glioma. Emerich does not disclose administering a formulation that comprises 5-FU and does not disclose a radiotherapy treatment after the administration of the carboplatin-loaded microspheres.

Boisdron-celle et al. "Preparation and Characterization of 5-Fluorouracil-loaded microparticles as Biodegradable Anticancer Drug Carriers," *J. Pharm. Pharmacol.* 1999, 47: 108-114) discloses a controlled release device comprising biodegradable microspheres that comprise PLGA (50% lactic acid and 50% glycolic acid) polymer and 5-Fluorouracil in stable emulsion for stereotactic injection and 5-Fluorouracil (5-FU) is used to treat common human glioblastoma, most common human glioma (abstract and pages 108-114). Regarding treating a human

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suffering from inoperable tumors, it is noted that Boisdstron-celle uses in vitro analysis to test the release pattern of 5-FU loaded PLAGA microspheres. However, the aim of the study is to be able to stereotactically implant the 5-FU loaded microspheres in the brain to treat brain tumors such as glioblastoma, which is the most common human malignant glioma and thus for eventual transference of the study to human subject. It is common practice to study therapeutic effects of drugs or chemotherapy in vitro model for transference to the human or other animal model. Boisdstron-celle differs from the instant claims by failing to teach administration of 5-FU loaded microsphere that is suspended in a sterile solution containing viscosity modifier, surfactant and isotonicity agent.

Response to Arguments

Applicants argue that the invention of Faisant I and Faisant II is not by another. However, Examiner differs from applicants' conception of invention by another in that the inventive entity of the examined application differs from the inventive entity of the co-pending application and issued application. See MPEP 2136.04 [R-1] which states that "Different Inventive Entity; Meaning of "By Another" IF THERE IS ANY DIFFERENCE IN THE INVENTIVE ENTITY, THE REFERENCE IS "BY ANOTHER." "Another" means other than applicants, In re Land, 368 F.2d 866, 151 USPQ 621 (CCPA 1966), in other words, a different inventive entity. The inventive entity is different if not all inventors are the same. The fact that the application and reference have one or more inventors in common is immaterial. Ex parte DesOrmeaux, 25 USPQ2d 2040 (Bd. Pat. App. & Inter. 1992). However, upon further consideration, the 131 declaration under 37 CFR 1.132 establishing that the relevant disclosure is applicant's own work, (In re Mathews, 408 F.2d 1393, 161 USPQ 276 (CCPA 1969)) overcomes

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the rejection under 35 U.S.C. 102(e). The outstanding obviousness type rejection described above remains. Regarding copending application 10/451,216, the rejection will not be held in abeyance until allowable subject matter is identified in the examined application and until the examined claims do not read on the copending claims.

IDS: Form PTO 1449 previously considered is made available to the applicant.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

